Remarks

Responsive to the Office Action dated June 2, 2006, Applicants request consideration of the following remarks. A reconsideration of the present application respectfully is requested. Claims 10-11, 13 and 17-20 previously have been canceled. Claims 21 and 22 previously have been added. As such, claims 1-9, 12-16 and 21-22 are pending and under consideration. Claims 1 and 12 have been amended. Applicants submit that no new matter has been added by way of these amendments. (See Page 6, Lines 13-15) Each of these claims are believed to be in condition for allowance and such favorable action is requested. Applicants would like to thank the Examiner and Examiner's supervisor for taking the time to interview the case on August 29, 2006. A copy of the interview summary is attached herewith.

103 Rejections

35 U.S.C. § 103(a) Rejections

To establish a *prima facie* case of obviousness, three criteria must be met:

1) there must be some suggestion or motivation to modify the reference or to combine reference teachings;

2) there must be a reasonable expectation of success; and

3) the prior-art references must teach or suggest all the claim limitations.

Moreover, the teaching or suggestion, and the reasonable expectation of success must be found in the prior art and not be based on Applicants' disclosure. *See* MPEP § 706.02(j), § 2142, and § 2143.

Claims 1-5 and 21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over by Sugi et al. (The American Journal of Gastroenterology, Vol. 91, No. 5, 927-934, 1996) (the "Sugi reference") in view of Kruzel et al. (Advances in Experimental Medicine and Biology, 1998, 443, pages 167-173, Abstract only.) (the "Kruzel reference"). As

neither the Sugi reference nor the Kruzel reference teach nor suggest a method for diagnosing irritable bowel syndrome if a fecal sample from a person presenting with symptoms common to inflammatory bowel disease (IBD) and irritable bowel syndrome (IBS) does not contain an elevated level of endogenous lactoferrin, Applicants traverse the rejection.

Claim 1 recites a method for diagnosing IBS by determining that a fecal sample from a person presenting with symptoms common to IBD and IBS does not contain an elevated level of endogenous lactoferrin.

When a patient presents with symptoms common to IBD and IBS, it is difficult to distinguish between the two conditions. Claim 1 of the present invention relates to diagnosing IBS when a patient presents with symptoms common to IBD and IBS if the level of fecal lactoferrin is not elevated for the patient. The prior art does not teach this. Specifically, the Sugi reference and the Kruzel reference do not teach measuring the level of lactoferrin in patients with IBS. Prior to the present application, it was unknown whether patients with IBS had elevated levels of lactoferrin. More specifically, while the Sugi reference teaches that fecal lactoferrin may utilized as a marker for disease activity in IBD as compared to healthy patients, the Sugi reference is silent as to whether patients with IBS have elevated levels of lactoferrin. Furthermore, as stated in the office action dated June 2, 2006, the Sugi reference does not teach the non-elevation of lactoferrin as indicating IBS in patients.

Likewise, the Kruzel reference does not teach that non-elevation of lactoferrin indicates IBS in patients presenting with symptoms common to IBD and IBS. Rather the Kruzel reference, like the Sugi reference, discusses lactoferrin's role in inflammation, but is silent as to whether patients with IBS have elevated levels of lactoferrin. A person of skill in the art could not develop a qualitative assay for diagnosing IBS in patients presenting with symptoms

common to IBD and IBS without determining whether patients with IBS have an elevated level of lactoferrin.

As the Sugi reference and the Kruzel reference neither teach nor suggest a method for substantially diagnosing IBS by determining a fecal sample from a person presenting with symptoms common to IBD and IBS does not contain an elevated level of endogenous lactoferrin, Applicants request withdrawal of the 103(a) rejection of claim 1. As claims 2-5 and 21 depend directly or indirectly from claim 1, Applicants request withdrawal of the rejection of these claims as well.

Claims 6-9 and 12, 14-16 and 22 have been rejected under 35 U.S.C. 103 (a) as being unpatentable over the Sugi reference in view of the Kruzel reference in further view of Peen et al., Gut, 1993, 34, 56-62 (the "Peen reference"). With respect to claims 6-9, as stated above, the Sugi reference and Kruzel reference do not teach or suggest diagnosing IBS by determining a fecal sample from a person presenting with symptoms common to IBD and IBS does not contain an elevated level of endogenous lactoferrin as claimed by independent claim 1 from which claims 6-9 depend.

With reference to claims 12, 14-16 and 22, amended claim 12 is drawn to an assay for obtaining a human fecal sample from a person presenting with symptoms common between IBD and IBS and determining whether an enzyme-linked antibody bound sample contains an elevated level of lactoferrin as compared to a reference value for health control subjects, wherein the optical density of the enzyme-linked antibody bound sample is read at 450 nm, wherein if said enzyme- linked antibody bound sample does not contain an elevated level of endogenous lactoferrin, IBS is diagnosed. As neither the Sugi reference in view of the Kruzel reference in further view of the Peen reference teach nor suggest a diagnostic assay for

diagnosing IBS if a fecal sample from a person presenting with symptoms common between IBD and IBS does not contain an elevated level of lactoferrin, Applicants traverse the rejection.

The Sugi reference does not teach or suggest a diagnostic assay for diagnosing IBS if a fecal sample from a person presenting with symptoms common between IBD and IBS does not contain an elevated level of lactoferrin. When a patient presents with symptoms common to IBD and IBS, it is difficult to distinguish between the two conditions. Claim 12 of the present invention relates to a diagnostic assay for diagnosing IBS when a patient presents with symptoms common to IBD and IBS if the level of fecal lactoferrin is not elevated for the patient. The prior art does not teach this.

Specifically, the Sugi reference, the Kruzel reference and the Peen reference do not teach measuring the level of lactoferrin in patients with IBS. Prior to the present application, it was unknown whether patients with IBS had elevated levels of lactoferrin. More specifically, while the Sugi reference teaches that fecal lactoferrin may utilized as a marker for disease activity in IBD as compared to healthy patients, the Sugi reference is silent as to whether patients with IBS have elevated levels of lactoferrin. Furthermore, as stated in the office action dated June 2, 2006, the Sugi reference does not teach the non-elevation of lactoferrin as indicating IBS in patients. Likewise, the Kruzel reference does not teach that non-elevation of lactoferrin indicates IBS in patients presenting with symptoms common to IBD and IBS. Rather the Kruzel reference, like the Sugi reference, discusses lactoferrin's role in inflammation, but is silent as to whether patients with IBS have elevated levels of lactoferrin.

The Peen reference also does not teach or suggest a diagnostic assay for diagnosing IBS if a fecal sample from a person presenting with symptoms common between IBD and IBS does not contain an elevated level of lactoferrin. The Peen reference merely teaches detecting high frequencies of IgG anti-lactoferrin antibodies, not lactoferrin itself, in serum

samples from patients with ulcerative colitis and primary sclerosing chloangitis. The Peen reference differs from independent claim 12 in that it detects IgG anti-lactoferrin antibodies in serum, not lactoferrin in fecal samples. The Peen reference also does not teach diagnosing IBS if a fecal sample from a person presenting with symptoms common between IBS and IBD does not contain an elevated level of lactoferrin as claimed by claim 12 of the present application.

As the Sugi reference in view of the Kruzel reference in further view of the Peen reference neither teach nor suggest a diagnostic assay for diagnosing IBS if a fecal sample from a person presenting with symptoms common between IBS and IBD does not contain an elevated level of lactoferrin, Applicants request withdrawal of the 103(a) rejection of claim 12. As claims 14-16 and 22 depend directly or indirectly from claim 12, Applicants request withdrawal of the 103(a) rejection as to these claims as well.

The present application is believed to be in condition for allowance, and Applicants request that a timely notice of allowance be issued for this case. Should any unresolved issues remain in the case, please feel free to contact the undersigned at the phone number listed below.

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Respectfully submitted,

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